

# **REGISTRATION REVIEW**

Report from PPDC Workgroup

Presentation to PPDC

October 29, 2003

# Registration Review Background

- FIFRA sec. 3(g) provides for periodic review of pesticides registrations
  - goal of every 15 years
  - establish a procedure via regulation
  - use data call-in authority to require data as necessary
  - other provisions of FIFRA apply
- Advanced Notice of Proposed Rule-Making (April 2000) –  
EPA's initial concept and solicit comments
- EPA presentation at April 2003 PPDC meeting
- Charge to form workgroup to make recommendations on key issues
- Workgroup formed in June 2003

# Background continued

- PPDC Workgroup organized in June 2003
  - 23 members; diverse membership
  - Series of public meetings held June – October 2003 to discuss and make recommendations for three key issues:
    - Criteria for scheduling registration reviews
    - Should there be multiple levels of the rigor of review depending on the pesticide and its issues?
    - What should be the stakeholder participation process?

# Background continued

- Other topics included:
  - What constitutes a registration review decision?
  - How to ensure that a pesticide's registration is kept up to date – registration review should be a safety net, not a catch-all
  - Accounting for inert ingredients in registration review.

# Workgroup Mission and Operation

- Mission: provide advice and recommendations on design and development of procedural regulations for registration review
- Three key issues:
  - How should pesticides be scheduled for review?
  - Should there be different levels of review?
  - How should the public participate?
- Four public meetings June - October 2003
- Discussion led to recommendations; did not seek group consensus

# **ISSUE 1**

## **How Will Pesticides be Scheduled for Registration Review?**

### **Considerations:**

- 1200 Pesticides / 20K Products subject to registration review
- Universe of pesticides continually changing
- Many chemically related pesticides
- Work group considered other alternatives, e.g., “worst first”

# Scheduling continued

- **Recommendations:**
- The administrative procedures for scheduling registration review should not be subjective, resource-intensive or time-consuming.
- Predictable schedule generally based on 15 years from date of registration, reregistration, or other major risk assessment
- Specific criteria for departure from scheduling should be established by regulation.
- Comprehensive schedule published in federal register and on EPA's website with regular updates

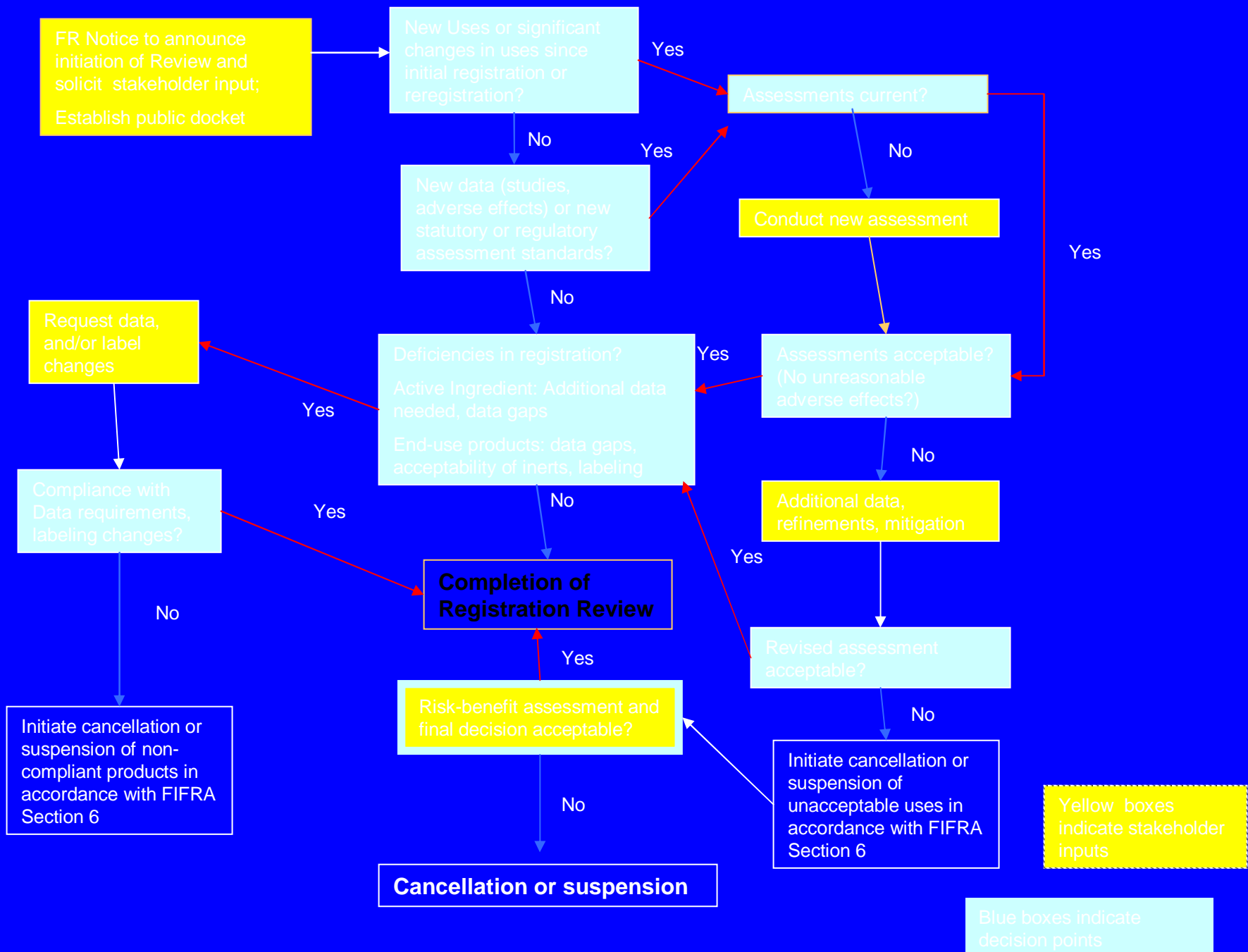
# **Issue 2**

## **Different Levels of Review**

Considerations:

- Not all chemicals pose the same risks
- Scope of the program mandates efficient use of resources
- Changes in data requirements, database, adverse effects data, science policies, and use and usage profiles





# Level of Review continued

## Recommendations:

- Registration Review process should allow for a streamlined review for relatively “simple” pesticides e.g., low toxicity, minimal usage
- Streamlined process for pesticides with stable regulatory history and science
- Pesticides with major complex issues would require a more robust assessment

# ISSUE 3

## How can meaningful public participation be accomplished?

- Considerations:

- Registration review would benefit from early participation by all stakeholders.
- Stakeholders need a predictable schedule to prepare for and participate in registration review.
- Stakeholders need an understandable process where opportunities and expectations for public participation are clear.

# Public Participation continued

- Recommendations:
  - Stakeholder input would be sought on use profiles, risk assessments, risk/benefit analyses, and risk mitigation measures.
  - Stakeholder process should be tailored to the level of review.
  - Modern electronic technology should be used to facilitate stakeholder access to information
  - Use of a comprehensive e-docket should be expanded to provide a continuum of information including history, status, public comments and all previous regulatory decisions of a pesticide
  - Publish a Federal Register Notice to initiate chemical specific registration review

# General Recommendations

- The review does not supersede or replace EPA's other authorities under FIFRA (data call-ins, special review, suspension, cancellation, etc.).
- Registration review can be considered a "safety net" so that every registration is reviewed periodically to assure that no administrative deficiencies or risk-related issues are overlooked.
- The degree of reassessment should not be a "one-size-fits-all" process

## GENERAL RECOMMENDATIONS - continued

- FRN should be published to announce annual or biannual updates to the schedule.
- Schedule should be made available on the EPA website well in advance.
- A predictable process and schedule for the submission of data by stakeholders
- Ensure the review of chemicals with outstanding issues (data call ins, etc.) will be completed in a timely manner

# Additional Issues

- What constitutes a registration review decision?  
Whether a pesticide meets the requirements of FIFRA section 3(c)(5)
- How to ensure that a pesticide's registration is kept up to date – registration review should be a safety net, not a catch-all
- Accounting for inert ingredients in registration review.

# Additional Issues

- What constitutes a current assessment?
- Possible criteria:
  - Dietary assessment: includes all current food uses
  - For assessments that are not dietary (residential, ecotox, endangered species concerns, occupational) includes uses that are the significant sources of exposure
  - No indications of significant new or increased adverse effects



# PPDC Discussion:

- Questions
- Discussion of key issues and workgroup's recommendations
- PPDC recommendations